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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,426	01/06/2004	Waldeman Priebe	PSPS:004USC1	3793

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/752,426	PRIEBE ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,17 and 48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,17 and 48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The abstract of the disclosure is objected to because it has not been presented in the proper domestic form. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: the status of the parent application Serial No. 09/956,588 has not been updated.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 17 and 48-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of U.S. Patent No. 6,673,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compounds are encompassed by the patented compounds.

Claims 1, 17 and 48-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R1 representing an alkyl chain, a (-COCH2R13) group or (C(OH)-CH2R13), does not reasonably provide enablement for R1 representing a nucleic acid intercalate or a topoisomerase inhibitor. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the invention;

Claims 1, 17 and 48- 57 are drawn to anthracyclines substituted by a nucleic acid intercalator or a topoisomerase inhibitor and their use.

(B) The nature of the invention;

The nature of the invention in such that it relates to compounds useful for treating cancer.

(C) The state of the prior art;

Anthracyclines substituted with a nucleic acid intercalator or a topoisomerase inhibitor are not known in the art.

(D) The level of one of ordinary skill;

One of ordinary skill in the art would be PhD or M.D.

(E) The level of predictability in the art;

It is well known that in case of pharmaceutical compounds even minor changes in the chemical formula can lead to major changes in the effectiveness of said compounds in treating a specific disease or condition.

(F) The amount of direction provided by the inventor;

The inventor has provided no direction on how to choose specific nucleic acid intercalators or topoisomerase inhibitors.

(G) The existence of working examples;

There are no working examples of specific nucleic acid intercalators and

(H) The quantity of experimentation need to make or use the invention based on the content of the disclosure.

It would take an undue amount of experimentation to determine which specific nucleic acid intercalators or topoisomerase inhibitors will result in a compound having the desired activity.

Claims 52-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer, does not reasonably provide enablement for preventing cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to use the full scope of the claimed invention without undue experimentation.

(A) The breadth on the claims;

The claims encompass prevention of cancer.

(B) the nature of the invention;

the nature of the invention is such that it reads on administering the substituted anthracycline to a healthy patient and preventing said patient from ever getting cancer.

(C) The state of the prior art;

While anthracycline compounds are known to be useful for treating cancer, said compounds are not known to be useful in preventing cancer.

(D) The level of one of ordinary skill;

One of ordinary skill in the art would be a Physician with an M.D./PhD.

(E) The level of predictability in the art;

There is no way to predict whether the claimed methods would be useful in preventing cancer.

(F) The amount of direction provided by the inventor;

The inventor provides no direction on choose healthy patients to whom administer the claimed compounds for the purpose of prevention of cancer. The inventor also fails to provide direction on whether the prevention if effective for days, weeks, months, years or whether permanent prevention is achieved.

(G) the existence of working examples;

There are no working examples directed to prevention of cancer and

(H) The quantity of experimentation needed to use the invention based on the content of the disclosure.

It would take an undue amount of experimentation by a person having ordinary skill in the art to determine whether the claimed methods are effective in preventing cancer i.e. it would require administration of the claimed compounds to healthy patients

and observing said patients for years to see if any of those patients have developed cancer.

Claims 48, 50 and 52-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "wherein the –XAAR substituent is disubstituted, trisubstituted, tetrasubstituted or pentasubstituted" (claims 48 and 50), "preventing cancer" (claims 52-57), preventing or treating in a patient breast cancer (claims 56-57), lung cancer, ovarian cancer, Hodgkin's disease, non-Hodgkin's lymphoma, acute leukemia or carcinoma of the testes (claim 56) is not disclosed or suggested by the application as originally filled.

Claims 1, 17 and 48-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprising" (claims 1 and 17, all occurrences) renders the claims indefinite since it renders the structural formula open-ended i.e. the scope of the invention cannot be determined.

The terminology "disubstituted, trisubstituted, tetrasubstituted,or pentasubstituted" renders claims 48 and 50 indefinite since substituents have not been set forth.

It is unclear if claims 49 and 51 are compound or composition claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200